

# Notice of Allowability

Application No.

10/715,818

Examiner

Leslie A. Royds

Applicant(s)

KREUTZ, WERNER

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 24 July 2006.
2. ☒ The allowed claim(s) is/are 54-56 and 58.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☒ Certified copies of the priority documents have been received in Application No. 09/466,570.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 17 October 2006.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

Leslie A. Royds  
Patent Examiner  
Art Unit 1614

17 OCT 06

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Eugene Lieberstein on Tuesday, October 17, 2006.

The following amendments have been authorized:

In the Specification:

Please amend page 1, first paragraph, to read:

---This invention is a divisional of U.S. patent Application Serial No. 10/371,088 filed on February 21, 2003, now US Patent No. 6,727,235, which itself is a divisional patent application of US patent application serial number 09/713,449 ~~09/413,449~~ filed on November 15, 2000, now US Patent No. 6,525,038, which is, in turn, a Continuation-In-Part of U.S. patent application serial number 09/446,570 filed on March 27, 2000, now U.S. Patent Number 6,395,720, which was filed as a 371 application of PCT/EP98/02939, filed March 27, 2000. The invention relates to novel synergistic compositions which selectively control tumor tissue, while healthy tissue is virtually unattacked. The novel compositions are therefore outstandingly suitable for cancer therapy.---

In the Claims:

(1) In claim 54, please add the word ---A--- in line 1 of the claim preceding the word "synergistic".

(2) In claim 55, please add the word ---A--- in line 1 of the claim preceding the word "medicament".

(3) Claim 56 should be amended to read:

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~~---A Method method of treating a human bladder tumor in a patient in need thereof comprising the step of administering to said patient in need thereof a pharmaceutically effective amount of a sensitive to the synergistic composition of 5-(2,4-difluorophenyl)salicylic acid in combination with 2,4,6-trihydroxybenzoic acid comprising the step of administering to a patient in need thereof a pharmaceutically effective amount of said synergistic composition.~~---

(4) Claim 58 should be amended to read:

~~---The Method method of treating a human bladder tumor in a patient in need thereof according to sensitive to the synergistic composition of claim 56, wherein said synergistic that composition is administered in a pharmaceutically tolerable excipient.~~---

#### Examiner's Statement Regarding Reasons for Allowance

The present application is allowed pursuant to Applicant's remarks presented in the amendment of July 24, 2006. Patentable distinction over the prior art has been established in view of the synergistic results demonstrated in human bladder tumor cell experiments using the combination of 5-(2,4-difluorophenyl)salicylic acid in combination with 2,4,6-trihydroxybenzoic acid. Please see, for example, Figures 4 and 5 of the drawings filed November 17, 2003.

Applicant's effective filing date has been granted to U.S. Patent Application No. 09/713,449, filed November 15, 2000. A comprehensive search of the prior art for either an explicit anticipatory teaching of the use of 5-(2,4-difluorophenyl)salicylic acid in combination with 2,4,6-trihydroxybenzoic acid was not found in the prior art. Additionally, the prior art did not provide any implicit suggestion of combining these two agents specifically for the treatment of human bladder tumor with the expectation of achieving the synergistic activity that Applicant has demonstrated (please see Figures 4 and 5, specifically, "Diflu + DHSA").

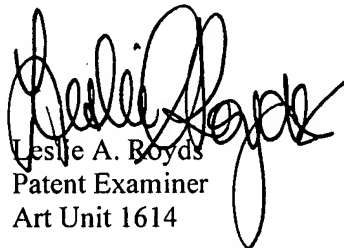
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For these reasons stated *supra* and those already presented in the record, claims 54-56 and 58 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Leslie A. Royds  
Patent Examiner  
Art Unit 1614

October 17, 2006

 10/22/06  
ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER